



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15BFV; Docket No. CDC-2015-0085]

**Proposed Data Collection Submitted for Public Comment and
Recommendations**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the proposed information collection request entitled "A Study of Viral Persistence in

Ebola Virus Disease (EVD) Survivors". The purpose of this information collection is to gather the necessary information for the CDC and the international community to begin the activities necessary to reach the goal of zero new EVD cases throughout West Africa. Once that goal is reached, the 42-day countdown to declare West Africa Ebola-free can begin.

"Persistence of Ebola Virus in Body Fluids of Ebola Virus Disease (EVD) Survivors in Sierra Leone". This information collection will be the first systematic examination of the post-recovery persistence of Ebola virus and the risks of transmission from a cohort of convalescent Ebola survivors during close or intimate contact.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0085 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.Regulation.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](https://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](https://www.regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](https://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the

Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of

collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Persistence of Ebola Virus in Body Fluids of Ebola Virus Disease (EVD) Survivors in Sierra Leone - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Much progress has been made in the year since the CDC first responded to the Ebola outbreak in West Africa, but the agency's efforts must continue until there are zero new cases of Ebola virus disease (EVD). As the CDC's 2014 Ebola virus response draws closer to the international goal of zero new EVD cases in 2015, the agency must intensify its efforts to identify and prevent every potential route of human disease transmission and to understand the most current community barriers to reaching that final goal.

``Persistence of Ebola Virus (EBOV) in Body Fluids of EVD

Survivors in Sierra Leone'' will be the first systematic examination of the post-recovery persistence of EBOV and the risks of transmission from a cohort of convalescent Ebola survivors during close or intimate contact. This activity is currently approved by OMB for emergency use under OMB Control Number 0920-1064 - Persistence of Ebola Virus (EBOV) in Body Fluids of EVD Survivors in Sierra Leone, which expires on November 30, 2015. It is important to fully understand how long the virus stays active in body fluids other than blood in order to target and refine public health interventions to arrest the ongoing spread of disease.

The research study is comprised of three modules based on the body fluids to be studied: A pilot module of adult males (semen) and two full modules: Module A of adult men and women repeating collections and questionnaires every two weeks (semen, vaginal secretions, and saliva, tears, sweat, urine, rectal swab), and Module B of lactating adult women repeating collections and questionnaires every three days (sweat and breast milk).

Participants for each module will be recruited by trained study staff from Ebola treatment units and survivor registries. Participants will be followed up at study sites in government hospitals.

Specimens will be tested for EBOV ribonucleic acid (RNA) by

reverse transcription polymerase chain reaction test (RT-PCR) in Sierra Leone at the CDC laboratory facility in Bo. All positive RT-PCR samples will be sent to CDC for virus isolation. Each body fluid will be collected until two negative RT-PCR results are obtained.

Participants will be followed until all their studied body fluids are negative. They will receive tokens of appreciation for their participation at the initial visit and again at every subsequent follow-up visit [e.g., 120,000 Leones (approximately \$28 US dollars) and a supply of condoms]. For Module A, men and women will be recruited in equal numbers for this study until more information on gender effects of viral persistence is available. A trained study data manager will collect test results for all participants in a laboratory results form.

Results and analyses are needed to update relevant counseling messages and recommendations from the Sierra Leone Ministry of Health, World Health Organization and CDC. The study will provide the most current information that is critical to the development of public health measures, such as recommendations about sexual activity, breastfeeding, and other routine activities and approaches to evaluation of survivors to determine whether they can safely resume sexual activity. These approaches in turn are expected to reduce the risk of Ebola resurgence and mitigate stigma for thousands of survivors. The

information is likewise critical to reducing the risk that Ebola would be introduced in a location that has not previously been affected. The total estimated annualized burden hours are 2,474.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Pilot participants	Survivor Questionnaire	80	1	30/60	40
Pilot participants	Survivor Follow-up Questionnaire	80	12	10/60	160
Module A male participants	Survivor Questionnaire	175	1	30/60	88
Module A male participants	Survivor Follow-up Questionnaire	175	12	10/60	350
Module A female participants	Survivor Questionnaire	175	1	30/60	88
Module A female participants	Survivor Follow-up Questionnaire	175	12	10/60	350
Module B female participants	Survivor Questionnaire	100	1	30/60	50
Module B female participants	Survivor Follow-up Questionnaire	100	12	10/60	200
Data manager	Laboratory Results Form	1	6,890	10/60	1,148
	TOTALS				2,474

Leroy A. Richardson,

Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

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